



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,305	07/10/2003	Yuko Taniike	43888-261	1627
20277	7590	01/11/2005		
MCDERMOTT WILL & EMERY LLP 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096			EXAMINER BARTON, JEFFREY THOMAS	
			ART UNIT 1753	PAPER NUMBER

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,305

Applicant(s)

TANIIKE ET AL.

Examiner

Jeffrey T. Barton

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20030710, 20040120
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 5 is objected to because in lines 2-3 of the claim, it refers to the second extension portion being in "left position or right position, corresponding to said specific substrate, in said length direction of said second base plate." The second extension portion was previously claimed as extending in a width direction (Claim 1, line 10), so it is unclear what the intended further limitation of this claim is. The claim is treated as though the limitation specified the *width* direction, not the *length*. Appropriate correction is required.
2. Claim 8 is objected to because of the limitation that "said specific substrate in said biosensor is discriminated by the position of said segmental portion of said sensor mounting portion". It is not clear how the position of the segmental portion can discriminate this - is it moved to actuate a switch that indicates the specific substrate? If the connection itself (i.e. completion of a circuit) upon insertion of the sensor provides the determination, the position of the segmental portion itself cannot be held to discriminate the substrate. Appropriate correction is required.
3. Claim 13 is objected to because of a typographical error in line 6 of the claim. It appears that "said first and said electrodes" should be replaced with "said first and said second electrodes". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-6, 8-10, and 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 at lines 8 and 11, and in claim 12, at lines 8 and 11, it is not clear whether the limitation "and has at least a part of said (first/second) lead exposed to outside" requires the lead to be disposed and exposed to the outside on the extension portion or simply somewhere on the base plate. The claims are treated herein as only requiring the lead to be disposed somewhere on the base plate.

6. Claims 3-10 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3 at lines 5-7 and claim 7 at lines 9-11, the terms "common part" and "non-common part" are indefinite, given the multiple definitions of "common". For instance, a plastic plate could be called a "common part", while a gold or platinum electrode could be called a "non-common part", when "common" is read as indicating relative abundance. It appears that applicants intend to claim that the shapes of the

Art Unit: 1753

plates are the same except for the protrusions, which are oriented differently, and the claims are treated as such herein. The wording of the claim also fails to indicate that the "common part" of the shape must be present on both shapes. (i.e. the first *and* second plates must have a shape having a common part)

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, and 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Lamos et al.

Regarding claim 1, Lamos et al disclose a biosensor comprising first and second insulating base plates with electrodes and leads disposed thereon as claimed (Figure 8A-C; electrodes 542 and either 550, 552, or 554; leads illustrated); wherein the first base plate has an extension portion extending in a length direction of the base plate from a position corresponding to an end of the second base plate in its length direction (Either 8A or 8C, tab at end opposite electrode end); and wherein the second base plate

Art Unit: 1753

has an extension portion extending in a width direction of the second base plate from a position corresponding to an end of the first base plate in its width direction. (Either Figure 8A or 8C - plates have widthwise extensions at the electrode locations)

Regarding claim 2, Lamos et al disclose widthwise extensions from opposite sides of the plates. (Figure 8A or 8C)

Regarding claim 11, Lamos et al disclose a measuring apparatus (Figure 16B; Column 21, lines 46-65) for a biosensor, comprising a sensor mounting portion (Figure 16B, connector 1500); for mounting the biosensor, wherein the mounting portion comprises a first sensor mounting segmental portion corresponding to the first base plate of the biosensor (e.g. left side with 3 upwardly bent contacts) and a second segmental portion corresponding to the second base plate (e.g. right side with 1 downwardly bent contact), wherein the portions have different widths.

Regarding claim 12, Lamos et al disclose using this apparatus with the biosensor described above. (Column 21, lines 48-54; Column 13, lines 6-14)

Regarding claim 13, Lamos et al disclose the measuring apparatus having connection terminals for contacting the leads, and a power supply for applying power to the electrodes. (Column 21, lines 46-56)

Regarding claim 14, Lamos et al disclose a processor and display coupled to the electrodes of the biosensor for performing computations based on the current and providing output. (Column 21, lines 56-65)

9. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Lauks et al.

Art Unit: 1753

Lauks et al disclose a measuring apparatus for a biosensor (Figure 1, unit 300) comprising a sensor mounting portion (360 and interior cavity) for mounting a biosensor comprising first and second base plates (Figure 3, top and bottom plates), wherein the sensor mounting portion comprises a segmental portion corresponding to each base plate, wherein the width of one segmental portion is different from the other. (Figures 3 and 11-13; given the different widths of the top and bottom sensor plates, the corner protrusions within the mounting apparatus shown in Figure 11 must correspond only to the top plate, leading to different widths of the upper and lower portions)

10. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Gotoh et al.

Gotoh et al disclose a measuring apparatus (Figure 15) for their biosensor, comprising a sensor mounting portion (11) for mounting the sensor (1), wherein the mounting portion comprises segmental portions corresponding to the two plates of the sensor (Electrodes 12, corresponding to sensor electrodes 2-4 in Figure 1a and 1b; Column 16, lines 33-41), wherein the segmental portions have different widths (Column 16, lines 33-41; since extension portions have different widths in the sensor shown in Figure 1a-c, the corresponding mounting portion would require segments of different width)

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1753

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1, 3-5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagata et al (JP-9-159642 and English abstract) in view of Nankai et al.

Relevant to claims 1 and 7, Nagata et al disclose a biosensor comprising first and second insulating base plates with electrodes and leads disposed thereon as claimed (Figure 1); wherein the first base plate has an extension portion extending in a length direction of the base plate from a position corresponding to an end of the second base plate in its length direction (Figure 1, plate 1b), and wherein parts of the first and second leads are exposed to the outside.

Relevant to claims 3 and 7, Nagata et al disclose a biosensor comprising a sample solution supply path for supplying a sample solution containing a plurality of substrates as claimed. (Figures 2 and 3, path 6, hole 62a)

Nagata et al do not explicitly disclose a second extension portion extending in a width direction from the second base plate from a position corresponding to an end of the first base plate.

Nankai et al disclose a similar biosensor wherein a tab extends widthwise from a second plate from a position corresponding to an end of the first plate. (Figure 1)
Nankai teaches the usefulness of such a tab in ensuring proper alignment of the sensor when inserting it into a corresponding measurement apparatus. (Column 2, lines 6-24)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Nagata et al by providing a widthwise-extending tab, as taught by Nankai et al, because it would facilitate proper insertion of the sensor into the measuring apparatus.

Regarding claims 3, 4, and 7, with respect to the limitations that the biosensor plates have a shape or extensions specifically positioned to correspond to a specific

Art Unit: 1753

substrate, these are not given weight in these claims to the sensor alone, inasmuch as their relevance exists solely in relation with a corresponding measurement apparatus that is not claimed here.

Regarding claim 5, Nankai et al show the second extension being in the left position, as viewed from the sample-introduction end of the sensor.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nagata et al and Nankai et al as applied to claim 3 above, and further in view of Gotoh et al.

Nagata et al and Nankai et al disclose a sensor as described above in addressing claim 3. Nagata et al also disclose detection of glucose using glucose oxidase in their sensor. (Paragraph 16, lines 9-12; see also enclosed computer translation)

Neither Nagata et al nor Nankai et al explicitly disclose detection of lactic acid.

Gotoh et al disclose sensors of similar design, and teach the use of different enzymes in reagent layers of sensors of this type for detection of different substrates. (Column 7, lines 11-23)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Nagata et al and Nankai et al by replacing the glucose oxidase with oxidase lactate for detection of lactic acid, as taught by Gotoh et al, because Gotoh teaches the usefulness of devices of this type in detecting lactic acid, and knowledge of lactic acid levels in the blood can be useful medical measurements, as admitted in Applicant's background section. (Page 1, line 18

Art Unit: 1753

- Page 2, line 1) Furthermore, selection of a suitable substrate from among known biosensor systems would be within the abilities of one having ordinary skill in the art.

16. Claims 1-10, 12-14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotoh et al in view of Lauks et al and Unno et al.

Relevant to claims 1, 7, and 12 Gotoh et al disclose a biosensor comprising first and second insulating base plates with electrodes and leads disposed thereon as claimed (Figures 1a-c, 2); wherein the first base plate has an extension portion extending in a length direction of the base plate from a position corresponding to an end of the second base plate in its length direction (Figure 1a or 1b), and wherein parts of the first and second leads are exposed to the outside.

Relevant to claims 3 and 7, Gotoh et al disclose a biosensor having a sample solution supply path for supplying sample solution containing a plurality of substrates such that the solution contacts the first and second electrodes, and a reagent that can react with a substrate. (Figure 2, 8 shows supply path; Column 3, lines 46-49; Column 4, lines 1-5) They also disclose base plates with shapes having common and non-common parts. (Figures 1a and 1b - common wider portion, non-common extensions)

Relevant to claim 6, Gotoh et al disclose detection of both glucose and lactic acid. (Column 7, lines 11-23)

Relevant to claims 8 and 17, Gotoh et al disclose a measuring apparatus (Figure 15) for their biosensor, comprising a sensor mounting portion (11) for mounting the sensor (1), wherein the mounting portion comprises segmental portions corresponding

Art Unit: 1753

to the common and non-common parts of the two plates of the sensor (Electrodes 12, corresponding to sensor electrodes 2-4 in Figure 1a and 1b; Column 16, lines 33-41; electrodes correspond to non-common parts, the conventional insertion slot allowing access to the connector part corresponds to the common part; Column 15, lines 44-65), wherein the segmental portions have different widths (Column 16, lines 33-41; since extension portions have different widths in the sensor shown in Figure 1a-c, the corresponding mounting portion would require segments of different width)

Relevant to claim 9, Gotoh et al disclose an apparatus having an integral fitting space for fitting the sensor thereto, wherein the space comprises a first region corresponding to the common part of the shape (entire width of mounting portion will match the sensor width, a common dimension to both plates), and a second region corresponding to the non-common part of the shape of one of the plates. (The connectors corresponding to electrode leads on either extension portion of a sensor as shown in Figures 1a-c)

Relevant to claim 10, Gotoh et al disclose a first electric connection terminal positioned for contact with said first region of the integral fitting space (e.g. connector to electrode 4 of Figure 1b - this lies within the width of the sensor, which is a common dimension of both plates, and can be seen as the common part of the shape) and a plurality of second electric connection terminals (e.g. connectors to electrodes 2 and 3 of Figure 1a)

Also regarding claims 9 and 10, there is no limitation saying that the first and second regions cannot overlap or comprise one region disposed within the other. The interpretation given above holds the second region as disposed within the first.

Relevant to claims 13 and 14, Gotoh et al disclose the measuring device having connection terminals for the leads and a power supply for applying a voltage to them; and a processor and display coupled to the electrodes of the biosensor for performing computations based on the current and providing output. (Column 15, line 31 - Column 16, line 45)

Gotoh et al do not explicitly disclose a biosensor wherein the second base plate comprises one or more extension in the width direction from positions corresponding to ends of the first base plate (Claims 1, 2 and 12); either base plate has a shape having a non-common part having a specific shape corresponding to a specific substrate (Claims 3, 7); either extension portion of the base plates is positioned at a specific position corresponding to a specific substrate (Claim 4); or the second extension is in a left or right position corresponding to a specific substrate (Claim 5). They also do not explicitly disclose a biosensor mounting apparatus wherein the specific substrate to be measured in the biosensor is discriminated by the position of the segmental portion of the sensor mounting portion corresponding to a non-common part of the shape of the first or second base plate or one of the plurality of second connection terminals connected to a lead. (Claims 8 and 10)

Lauks et al teach a biosensor and measurement apparatus wherein the specific measurement is indicated to the measurement apparatus by the specific shape and

arrangement of notches positioned on a plate of the sensor. (Figure 4a, notches 28, 30, 32, and 34; Column 6, line 54 - Column 7, line 11) The positioning of the notches provides or prevents connections that indicate the specific substrate to the reader. They also teach widthwise or lengthwise positioning of the notches (e.g. 28, 30 are lengthwise, 36, 38 are widthwise; Figure 4a)

Unno et al teach microfluidic devices and control systems wherein complementary tabs, notches, pins, posts, and the like are used in the plates and control system to determine the type of operation to be performed in the device. (Column 5, lines 5-57)

Regarding claims 1, 2, and 12, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biosensor of Gotoh et al by providing widthwise indicators on the second plate (Figure 4a, notches 36, 38), as taught by Lauks et al, because choice of specific shape of the sensor lies within the abilities of a skilled artisan. Furthermore, Lauks et al teach the usefulness of such widthwise notches in providing necessary connections and indication of substrate, as further described below. Replacement of the notches of Lauks et al with tabs would also constitute an obvious change in shape (See Unno et al), as the specific shape of such indicating structures would also be a design choice within the abilities of one having ordinary skill in the art.

Regarding claims 3 and 7, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor of Gotoh et al by using one of the non-common parts of one of the plates to indicate a specific substrate

to be measured to the measurement apparatus, as taught by Lauks et al, because Lauks et al teach the usefulness of such a configuration in enabling the use of a single measurement apparatus for plural measurements, leading to an efficient sensing system. (Summary section; Column 6, line 54 - Column 7, line 11) Replacement of the notches of Lauks et al with tabs would also constitute an obvious change in shape (See Unno et al), as the specific shape of such indicating structures would also be a design choice within the abilities of one having ordinary skill in the art.

Regarding claims 4 and 5, specific number and positioning of these indicating structures would be a matter of design choice to one having ordinary skill in the art.

Regarding claims 8, 10 and 17, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the measuring apparatus of Gotoh et al by using one of the non-common parts of one of the plates to indicate a specific substrate to be measured to the measurement apparatus, as taught by Lauks et al, because Lauks et al teach the usefulness of such a configuration in enabling the use of a single measurement apparatus for plural measurements, leading to an efficient sensing system. (Summary section; Column 6, line 54 - Column 7, line 11) Replacement of the notches of Lauks et al with tabs would also constitute an obvious change in shape (See Unno et al), as the specific shape of such indicating structures would also be a design choice within the abilities of one having ordinary skill in the art. Specific to claim 10, Lauks et al teach electrical connections provided by the notches for indication. (Column 6, lines 61-68)

Art Unit: 1753

17. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liamos et al in view of Zelin.

Liamos et al disclose a measuring apparatus as described above in addressing claim 12.

Liamos et al do not explicitly disclose any sort of ejection member within the measuring apparatus.

Zelin discloses a biosensor measurement apparatus wherein an ejection member is provided for automatically removing a sensor from the mounting portion after the measurement is complete. (Column 7, lines 7-10)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Liamos et al by providing an automatic ejection system for expelling biosensors after the measurement was complete, as taught by Zelin, because it would facilitate use of the sensors and minimize physical contact with test strips.

18. Claims 15 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Gotoh et al, Lauks et al, and Unno et al as applied to claim 12 above, and further in view of Zelin.

Gotoh et al, Lauks et al, and Unno et al disclose a combined measuring apparatus as described above in addressing claim 12.

None among Gotoh et al, Lauks et al, and Unno et al explicitly disclose any sort of ejection member within the measuring apparatus.

Zelin discloses a biosensor measurement apparatus wherein an ejection member is provided for automatically removing a sensor from the mounting portion after the measurement is complete. (Column 7, lines 7-10)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combined apparatus of Gotoh et al, Lauks et al, and Unno et al by providing an automatic ejection system for expelling biosensors after the measurement was complete, as taught by Zelin, because it would facilitate use of the sensors and minimize physical contact with test strips.

Regarding claim 16, the specific location of the application of the push out force would be a matter of design choice to one having ordinary skill in the art. An extension of the substrate disposed within the measuring apparatus during measurement would be a convenient and obvious choice.

Conclusion

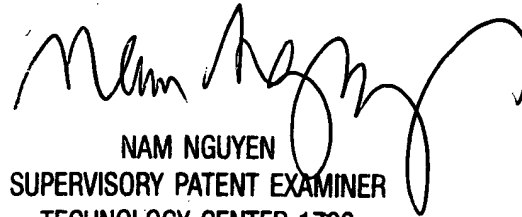
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 1753

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
January 10, 2005



NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700